MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT
NOTIFICATION DATE: March 27, 2014
EFFECTIVE DATE: Immediately

Solid Tumor Targeted Cancer Gene Panel by Next Generation Sequencing

Test ID: CANCP

USEFUL FOR:

- Identifying tumors that may respond to targeted therapies by assessing multiple gene targets simultaneously
- Identifying specific mutations within genes known to be associated with response or resistance to specific cancer therapies
- Identifying mutations that may help determine prognosis for patients with solid tumors
- Assisting in establishing a diagnosis (eg, KIT and PDGFRA alterations for gastrointestinal stromal tumors)

METHODOLOGY: PCR-Based Next Generation Sequencing

REFERENCE VALUES: An interpretive report will be provided.

SPECIMEN REQUIREMENTS: **Pathology report must accompany specimen in order for testing to be performed.**

Preferred:
Specimen Type: Tissue
Container/Tube: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block.

Acceptable:
Specimen Type: Tissue
Container/Tube: Slides
Specimen Volume: 1 stained and 10 unstained
Collection Instructions: Submit 1 slide stained with hematoxylin and eosin and 10 unstained, non-baked slides with 5-micron thick sections of the tumor tissue.

NOTE: Forms: New York Clients-Informed consent is required. Please document on the request form or electronic order that a copy is on file. An Informed Consent for Genetic Testing (Supply T576) is available in Special Instructions.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Varies	Ambient (preferred)	
	Frozen	
	Refrigerated	

CAUTIONS:

- This test cannot differentiate between somatic and germline alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.
- DNA variants of uncertain significance may be identified.

- A negative (wild-type) result does not rule out the presence of a mutation that may be present but below the limits of detection of this assay (approximately 5%-10%).
- This test does not detect large single or multi-exon deletions or duplications or genomic copy number variants.
- Rare polymorphisms may be present that could lead to false-negative or false-positive results.
- Test results should be interpreted in the context of clinical findings, tumor sampling and other laboratory data. If results obtained do not match other clinical or laboratory findings, please contact the laboratory for updated interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

CPT CODE:
Solid Tumor Targeted Cancer Gene Panel by Next Generation Sequencing
81210- BRAF (v-raf murine sarcoma viarl oncogene humolog B1) (eg, colon cancer), gene analysis, V600E variant
81235- EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
81245- FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis, internal tandem duplication (lTD) variants (ie, exons 14, 15)
81270- JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
81275- KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (eg, carcinoma) gene analysis, variants in codons 12 and 13
81310- NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis; exon 12 variants
81403- ABL1 (c-able oncogene 1, receptor tyrosine kinase) (eg, acquired imatinib tyrosince kinase inhibitor resistance) varients in the kinase domain
81403- CTNNB1 (catenin [cadherin-associated protein], beta 1, 88kDa) (eg, desmoid tumors), targeted sequence analysis (eg, exon 3)
81403- GNAQ(guanine nucleotide-binding protein G[q] subunit alpha) (eg, uveal melanoma), common variants (eg, R183, Q209)
81403- HRAS (v-Ha-ras Harvey rat sarcoma viral oncogene homolog) (eg, Costello syndrome), exon 2 sequence
81403- IHD1 (isocitrate dehyrogenase 1 [NADP+], soluble) (eg, glioma), common exon 4 variants (eg, R132H, R132C)
81403- IHD2 (isocitrate dehyrogenase 2 [NADP+], mitochondrial) (eg, glioma), common exon 4 variants (eg, R140W, R172M)
81403- MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence
81404- FGFR2 (fibroblast growth gactor receptor 2) (eg, craniosynostosis, Apert syndrome, Crouzon snydrome), targeted sequence analysis (eg, exon 8, 10)
81404- FGFR3 (fibroblast growth gactor receptor 3) (eg, achondroplasia, hypochondroplasia), targeted sequence analysis (eg, exon 8, 11, 12, 13)
81404- KIT (C-kit) (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, GIST, acute myeloid leukemia, melanoma), targeted gene analysis (eg, exons 8, 11, 13, 17, 18)
81404- NRAS (neuroblastoma RAS viral oncogene homolog) (eg, colorectal carcinoma), exon 1 and exon 2 sequence
81404- PDGFRA (Platelet-derived growth factor receptor alpha polypeptide) (eg, gastrointestinal stromal tumor), targeted sequence analysis (eg, exons 12, 18)
81404- RET (ret proto-oncogene) (eg, multiple endocrine neoplasia, type 2B and familial medullary thyroid carcinoma), common variants (eg, M918T, 2647_2648delinsTT, A883F)
81405-TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons
81479- Unlisted molecular pathology procedure code

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81479-Unlisted molecular pathology procedure code
Slide Review
88381-Microdissection, manual

DAY(S) SET UP: Monday through Friday **ANALYTIC TIME**: 12 days

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Marvin H. Anderson, Jr., MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710